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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,491	01/18/2001	Jack L. Arbiser	EU 98055 CON	8772

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EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/21/2001

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,491

Applicant(s)

ARBISER, JACK L.

Examiner

Jennifer M Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 10-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6, 10-12 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

DETAILED ACTION

Claims 4-6 and 10-17 are presented for examination.

Applicant's election with traverse of Group I (claims 4-6, 10-12 and 17), a method for inhibiting skin disorders comprising administering angiogenesis inhibitor in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the claims of Group I and Group II should be examined together since there is critical limitation in the composition claims that require that the active agent be presented in an amount effective to treat skin disorders that is unique to that purpose and via that means of application. However, this is not found persuasive because the inventions in Group I and Group II are distinct and independent since the product as claimed can be used in a materially different process using that product since the product has been used for treatment of bladder cancer and topical treatment of scleroderma. Therefore, the restriction requirement is deemed proper.

Accordingly, claims 4-6, 10-12 and 17 have been examined since they are claims of elected Group I. Group II, claims 13-16 is withdrawn from consideration.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 4-6, 10-12, and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4,5,7-9, and 17 of copending Application No. 09/345,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite since it is not clear which is the active agent being administered.

Claims 11 and 12 recite the limitation "the angiogenesis inhibitor" in claim 10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4-6, 10 and 11 are rejected under 35 U.S.C. 102(b) as being unpatentable by Aggarwal et al. (WO 95/18606) of record, and Andrulis, Jr. et al.(U.S. Patent No. 5654312) of record.

With regard to claims 10 and 11, Aggarwal et al. on page 5, line 20 through page 6, line 11, and page 7 lines 26-30, teaches the use of curcumin or an analogue thereof to treat psoriasis, basal cell carcinoma, and squamous cell carcinoma topically.

With regard to claims 4-6, Andrulis, Jr. et al. teaches on the abstract, column 1, lines 47-48, lines 55-56, that Thalidomide is effective inhibitor of angiogenesis.

Andrulis, Jr. et al. also teach on column 4, lines 55-60, and column 6, line 18, line 43 and line 57, teach thalidomide may be administered topically to treat eczema and rosacea.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10120558A of record.

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With regard to claim 4 and 5, JP 10120558A , teaches external curcumin composition is useful for treating eczema.

The difference between above reference and Applicant's claimed invention is an effective amount of curcumin to treat eczema.

However, a skilled artisan would have been motivated to determine the effective amount of curcumin in view of the reference to achieve beneficial effect of treatment in eczema with reasonable expectation of success.

2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aggarwal et al.(WO 95/18606) of record.

Aggarwal et al. on page 5, line 20 through page 6, line 11, and page 7 lines 26-30, teach the use of curcumin or an analogue thereof to treat various types of neoplastic diseases including sarcomas and non-neoplastic diseases such as psoriasis, basal cell carcinoma and squamous cell carcinoma.

The difference between above reference and Applicant's claimed invention is specific analogue set forth in claim 12. However, the skilled artisan would be motivated to employ Applicant's well known analogue of curcumin set forth in claim 12 in treatment of neoplastic disease such as psoriasis, basal cell carcinoma and squamous cell carcinoma since Aggarwal et al. teach that an analogue of curcumin is useful in treatment of various types of neoplastic diseases including sarcomas and non-neoplastic diseases such as psoriasis, basal cell carcinoma and squamous cell carcinoma.

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3. Claims 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admission and Pharmacotherapy(1989).

Applicant admits on page 6, lines 6-8, lines 18-26, and page 7, line 10, teach that tetracyclines or minocyclines are collagenase inhibitors.

Pharmacotherapy on page 960 right hand column (Topical Antibiotics) through page 961 left hand column (Oral Antibiotics) teaches **tetracyclines** and derivatives including minocyclines useful for treating **acne**.

The difference between above reference and Applicant's claiming invention is the effective amount of tetracyclines to treat acne. However, the amounts of active agents to be utilized in treatment of medical disorders are within the knowledge of a skilled artisan. The skilled artisan would have been motivated to determine the effective amount of tetracycline to utilize in treatment of acne as taught by above reference.

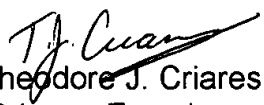
For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer M Kim whose telephone number is 703-308-2232. The examiner can normally be reached on 8:30AM - 5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

jmk
November 16, 2001